AMENDMENT OF NIAID SOLICITATION
RFP-NIH-NIAID-DAIDS-05-06
Amendment #1 (Questions & Answers)

"HIV Clinical Research Management Support"

This Amendment provides questions submitted by potential offerors and the responses provided by the NIAID. The responses are offered for information only and do not modify or become part of this solicitation.

Amendment Number:	One (2nd Posting)
Amendment Issue Date:	August 6, 2004 (Questions 1 – 98) September 8, 2004 (Questions 99 – 109)
Proposal Due Date/Time:	September 17, 2004, 3:00P.M., EST (Unchanged)
Issued By:	Elizabeth J. Shanahan Contracting Officer RRCB/CMP/DEA/NIAID/NIH/DHHS 6700-B Rockledge Drive, Room 3214, Bethesda, Maryland 20892-7612
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The hour and date specified for receipt of proposals HAS NOT been extended. Offerors must acknowledge receipt of this amendment by noting, on the face page of the original technical and business proposals, that the proposal has been prepared in accordance with the original solicitation and all of its Amendments. Failure of the offeror to submit this acknowledgment may result in the rejection of their proposal.

PURPOSE OF AMENDMENT: To transmit to all Offerors the responses to Questions that have been submitted concerning the solicitation. See Attached.

GENERAL ISSUES		
No.	**Question**	**Answer**
1.	Does a joint venture company as a legal single entity qualify as a prime to meet the core requirements?	Offerors must use their own judgment in determining if they can fulfill the requirements of the Mandatory, and all other evaluation criteria.
2.	With respect to an offeror's in-house capacity and expertise to perform non-core functions, does the government wish to see a technical approach component in Section Two of the technical proposal? Alternatively, should Section Two be limited to the discussion of managing resources to fulfill the requirement of the non-core functions?	The offeror should discuss how a program management core would be constituted and provide a technical approach that would in turn demonstrate how this "core function" will respond to the requests from the government for non-core functions and how the offeror would react responsively to "unknown" requirements, i.e., through describing (not identifying) viable subcontractors or utilizing in-house expertise, dependent upon the nature of the work and on a case-by-case basis.
3.	Are all clinical trials sites, including those in non-U.S. locations, subject to HIPAA privacy rules? Is the contractor responsible for assuring HIPAA compliance at the sites?	Please see page 52, Section L, 2.a.(9).
4.	Are resumes and past performances included in the 150 page limit?	Yes. The Technical Proposal only requires resumes of Key Personnel and they may be limited to 2-3 pages each.
5.	Please confirm the type of cost reimbursement contract you intend to award-CPAF or CPFF?	Refer to Section L.2.a.(1) of the RFP. We plan to award a cost-reimbursement type contract. Whether a fee is involved will be determined by the type of organization receiving the award. It is not intended that this contract be a performance based, award fee type contract.
6.	Can an existing organization refer to the past performance of key personnel offered if such past performance is relevant but was accomplished outside the existing organization?	Yes. Please refer to SECTON L,a.(19) Past Performance Information.
7.	Are organizations that are currently managing or performing clinical trials within the scope of this RFP precluded from bidding on the basis of an actual or perceived conflict of interest?	No, In the event of perceived organizational conflicts of interests offerors are required to self-identify these conflicts and submit a mitigation plan as part of their proposal.
8.	SOW Section One, B,2. and Section Two, A.7.: With many Non-Core activities including facilities management required at non-U.S. locations and priority being given to small and/or disadvantaged businesses, when subcontracts are utilized what are the guidelines for use of non-U.S. service firms?	The prime contractor is required to make subcontracting with Small Businesses a priority in order to meet the goals stated in the Small Business Subcontracting Plan included in this RFP. It is anticipated that the use of non-U.S. service firms will be necessary. The prime is expected to balance the use of subcontractors in compliance with all terms and conditions of the contract.

GENERAL ISSUES		
No.	**Question**	**Answer**
9.	The RFP mentions that the DAIDS needs easy and rapid access to Management Core Staff. Which positions do you deem as Management Core Staff?	Appendix B provides estimated direct labor categories for Core Functions. The offeror should identify their representation of "Management Core Staff" in their proposal.
10.	For the core function statement of work deliverables the due dates noted for some of the tasks are within so many months of the effective date of the contract, does this mean the prime contract?	Yes.
11.	For what phases of study development/execution will SOPs be required? Should it be assumed this does not include protocol development and/or site registration?	The SOPs will potentially be required for Phase I-III clinical trials. Please refer to the SOW, Section One, paragraph A.5., concerning the assumption that protocol development/site registration is included.
12.	Section Two (SOW) and the Reporting Requirements and Other Deliverables, Item (e.) list the Due Dates after the contract award for: • Standardized Clinical Trials SOPs (6 months) [A.5.] (deliverable) • Site Comparison Report Format (3 months) [A.4.g.] (deliverable) • Site Comparison Reports (10 days after each Quarterly Report) [A.4.g.] (deliverable)… Please explain the chronology.	Information in the Site Comparison Report would be based, in part, on compliance with SOPs. Please refer to your own internal SOPs to determine logical chronology. Sites shall be monitored to determine compliance with site (and network) SOPs. Standardization of SOPs will be an area of concentration for the contractor.
13.	Will the contractor project team, eg, biostatistician, be unblinded for DSMB presentation or another unblinded biostatistician independent of project biostatistician is needed for interacting with DSMB.	The contractor will be furnished with a SOP if this task is exercised.
14.	Must all data (clinical data, project management data, communications web site, training materials web site etc.) be hosted at the centralized facility (on the contractor's site), or alternatively, may the data be hosted at a secure commercial hosting facility? May the contractor make this decision?	Offerors should propose their approach in their technical proposal. A final decision will be made after award of contract in consultation with DAIDS.
15.	On pages 30, 31 of the RFP, please clarify that all deliverables under Section 2, non-core functions, are due only if the government has required that this contract carry out the assigned work. Our confusion stems from, e.g., Site Oversight Report, Site Expenditure report, and Monthly Monitoring Deficiency Report. We would assume that these reports are due only of the government has asked the contractor (via the request form) to perform activities under Section Two Paragraph A or Paragraph C of the SOW.	The deliverables are only due if a requirement for services has been identified by the Government.

GENERAL ISSUES		
No.	**Question**	**Answer**
16.	Is the Contractor responsible for ensuring IT and data security at all data collection sites?	The contractor may be directed to establish processes to assure adequate IT and data security at multiple data sites based on the terms of the sites' individual agreements. This cannot be determined until after award.
17.	Are there any special requirements regarding data backup, data storage, data retention?	Data collected may be utilized towards licensure of a pharmaceutical product. It is anticipated that the contractor will fulfill all U.S. Federal requirements for data handling. Section Two, B.1., provides information on this task.
18.	Does DAIDS envision support for a Web based system for project management data (i.e., not clinical data, but management data) collection and dissemination through this contract?	The use of a web based system for project management data is possible but offerors should refer to Section L.2.a.(5), Alternate Proposals (pg. 51 of the RFP) for direction on proposing an Alternate Proposal.
19.	On page 3 of the RFP, the document states that the "Contractor must have a significant base of international research management expertise, especially on the ground in resource poor, underdeveloped countries." Is "international research management" specific to clinical trials or research inclusive of epidemiology and evaluation?	Clinical Trials experience is necessary.

STATEMENT OF WORK: SECTION ONE – CORE FUNCTIONS		
No.	**Question**	**Answer**
20.	Page 7, Section A, Item 1. Please clarify if these contract management activities include the Non-Core functions.	As stated in the referenced paragraph the contract management functions require the offeror to "Manage, oversee and monitor all contract activities on a daily basis." Contract management activities do not include performance of the non-core functions.
21.	Page 7, Section A, Item 4. Please clarify the terms, "Network" and "non-Networks" and provide examples of each term.	Please refer to Appendix C, Items 9 and 10.
22.	Page 7, Section A, Items 4 and 5. Please clarify the format for these procedures.	It is up to each offeror to develop the format for their standardized policies and procedures. For both Items 4 and 5 it is anticipated that the formats will be discussed with the Project Officer after contract award and prior to the required submission dates.
23.	Page 8, Section B, Item 4, please clarify if the Government will be participating on the technical review panels.	It is not anticipated that Government representatives will be participating in the technical review panels, but the Contracting Officer (with the Project Officer's recommendation) will have final consent of any awarded subcontract.
24.	Page 10; please clarify if a Transition Plan is required at the start of this contract. If this is a requirement, recommend adding 10 pages to the 150 page count to provide sufficient space to provide a detailed start-up Transition Plan.	The Initial Transition Plan shall be developed within twenty-four (24) months after contract award. There is no requirement that the Initial Transition Plan be submitted as part of the proposal.
25.	Is there an expedited review process for requesting and selecting subcontractors? Will we always have to perform market research to identify potential subcontractors or would there be instances where subcontractors may be used based upon proven record and experience with the government?	All subcontracts shall be acquired and managed as outlined in the Statement of Work, Section One, B.4. (pages 8 and 9) and in accordance with FAR 52.244-2.
26.	While the Project Manager cannot serve on the Technical Review panel (p. 9) please confirm whether any other individual from the contractor's institution may serve?	Individuals from the prime contractor's organization could potentially serve on the Technical Review Panel established for the review of proposals to perform non-core functions. However, consideration will be given to ensure that no conflicts of interest exist.
27.	SOW Section One, A.9.: Meeting management services are a Core Function. With the international scope of the RFP, has consideration been given to making meeting planning a Non-Core Function so it could be subcontracted to a firm that specializes in this activity?	Meeting management is not intended to be included as a core function. Paragraph A.7. refers to the coordination of meetings necessary for the oversight and management requirement of the core functions. Section Two, C.1.b., addresses other meeting requirements anticipated by the SOW.

STATEMENT OF WORK: SECTION ONE – CORE FUNCTIONS		
No.	**Question**	**Answer**
28.	SOW Section One, B,4.: Are travel expenses and honoraria for Technical Evaluation Panel members reimbursable under this contract?	Yes.
29.	SOW Section One, A.8. & A.9.: What are the projected number, size and locations of meetings/year?	We are unable to make projections other than those provided in the Uniform Budget Assumptions provided in Appendix B.
30.	SOW Section One, B.4.: For subcontracts exceeding $500,000 a technical review panel is required. Does the $500,000 refer to the life of agreement or an annual basis and is it based on total cost?	The $500,000 refers to the total cost for the life of the agreement.
31.	SOW Section Two, A.: What will be the funding source(s) for new sites, and if they are funded through this contract will a technical review panel be required for awards that exceed $500,000?	This contract will not be the funding source for new clinical sites. Sites will be funded under other mechanisms such as grants, cooperative agreements and other contracts.
32.	SOW Section One, A.4.: Does ensuring compliance with State Department travel guidelines include honoring State Department travel warnings?	Yes.
33.	SOW Section One, A.4.: It is clear that this task encompasses standardization of site and network evaluation programs. Since it will be necessary to interact with multiple contractors and grantees in order to obtain this information for site evaluation, is the expectation that this Contractor will be not only the coordinating center for these tasks, but also that this Contractor will direct the work of the contractors providing the data? An example of this would be a data management center that provides data quality scores but the format is not the most desirable one in which to provide an opportunity for evaluation. Would this Contractor be expected to direct the data management center staff to revise the format?	The prime contractor will be responsible for managing and overseeing the work of their subcontractors. At no time will the prime contractor be expected to direct the work of other contractors providing services to the DAIDS. Technical direction will come from the appropriate personnel at the NIAID. It is expected that the prime contractor will be making recommendations to the Project Officer of this contract how they can most effectively coordinate/cooperate and work with other contractors in order to accomplish the requirements of the SOW. In turn the Project Officer will take the necessary actions.

STATEMENT OF WORK: SECTION TWO – NON-CORE FUNCTIONS		
No.	**Question**	**Answer**
34.	For the non-core function of site identification/ assessment and site and study preparation there is a note that states the contractor shall not prepare or assist the site in the grant application. It is not clear what the grant application would cover, especially for a single study. What would the contractor's responsibility be regarding collection of the regulatory documents required for a specific protocol? And what is the financial mechanism for these sites to receive money to conduct the research (would the contractor be responsible for this?)	The contractor may collect regulatory documents on a case-by-case basis; at this time the DAIDS utilizes the Regulatory Compliance Center to collect documents for Network trials. This contract may at some point collect key documents for non-network trials although that has not been determined at this point. Typical essential documents such as Investigator CV, Laboratory Values, etc. are considered key documents that show compliance with U.S. Federal Guidelines (Good Clinical Practices). Funding for specific sites would not be provided through this contract.
35.	Under non core activities on page 13, Section Two, A.2.4., "characterizing populations for potential study including.....Surveys...." Is the contractor to design (or use pre existing data collection tools), acquire OMB clearance, and collect the surveys?	Yes, at the request of DAIDS and working with Principal Investigators.
36.	Section Two, A.3.b., states 'Coordinate Contractor activities at clinical trial sites…'. Many of the functions are performed by other DAIDS contractors (Drug Distribution, tracking of submissions to IRBs/IECs and monitoring report tracking). Can the general scope of these activities be projected and what the responsibilities under this contract for managing other contracted work?	The general scope of these activities is as defined it the SOW. The NIAID does not have the ability to quantify or project the activities at this time that is why we have provided prospective offerors with the Uniform Budget Assumptions to be used in proposing costs for the non-core functions. The prime contractor will not have responsibilities for managing the work of other contractors (other than their own subcontractors).
37.	SOW Section Two, A.5., Financial Management: Will the DAIDS provide the contractor with detailed budget information and the Administrative Terms of Award for each clinical site and network award?	Yes.
38.	SOW Section Two, A.5.: Will financial management include authorizing payments to sites? Will it also include making payments to sites/investigators?	Financial management includes collecting, organizing, and reporting site financial information. The contractor will not be responsible for authorizing or making payments to sites.
39.	SOW Section Two, A.5., Financial Management: Could you provide examples of the type of reports that will be needed on a periodic basis.	We do not have sample reports. The format for the report will be discussed and agreed upon with the successful offeror subsequent to award.
40.	SOW Section Two, A.5.c.: Site Expenditure reports are due monthly from the contractor. Will the Terms of Award for each network site, non-network site and each network specify the expenditures to be tracked monthly and provided to the contractor?	The NIAID will be providing the Terms of Award for each site. It is anticipated that after award of this contract the contractor will work with the Project Officer in determining what specific expenditures are to be reported in the development of a format for financial reports. Further, the contractor will work with the sites in establishing routine reporting procedures.

STATEMENT OF WORK: SECTION TWO – NON-CORE FUNCTIONS		
No.	**Question**	**Answer**
41.	SOW Section Two A, 7.c.: In general, how much computer equipment for the sites is the Contractor expected to provide or offer advice in acquiring for this contract? What about technical support (as opposed to service contracts) for the use of computer equipment? Is it expected that technical support be provided? What type of specialized technical equipment is expected to be included in this? Lab equipment, health monitoring equipment, computers, etc?	On-site technical support may be required for short periods of time. The contractor will be expected to identify the needs and assist the sites in obtaining the resources. Costs for purchase of equipment will be borne by the sites.
42.	SOW, Section Two, B.1.c.: Please clarify the requirement to "Serve as a central processing station for data collection tools ...." For example, does this mean that a single data repository is desired which will store common elements from all trials, whether Network, Non-Network or investigator-initiated trials? If so, will vendors migrate data from existing data management (DM) systems into this repository on an ongoing basis for all applicable trials; and will they also provide data accession / entry services for trials not currently served by an acceptable (validated) DM system?	The DAIDS is moving towards standardization of systems utilized in the conduct of clinical trials. The identification of common data elements and standardization of data collection tools will be important. The DAIDS wants to increase commonality of data collected for ease of cross-analysis, across networks and between non-network trials if warranted. One mechanism to move towards this goal is to offer an interim data collection point for sites so that "pluripotent" sites (a site conducting multiple trials with multiple networks) can simply upload all data to one data processing station, which then may distribute data to different Data Management Centers. That station would then interface with multiple data centers to transfer the data, or assist the "pluripotent" sites in multiple ways. It is possible that there may be a request to migrate data from existing data management (DM) systems into a repository on an ongoing basis for applicable trials.
43.	SOW Section Two, B.1.e.: Should it be assumed that 'validation' is Compliance with CFR, Title 21, Part 11?	Yes.
44.	SOW Section Two, B.1.e.: "Provide technical support and assessment advice to the sites as related to data management services." C can you expand on technical support? For example, is this limited to system assessment and implementation or does this include such support as a system or software help desk, training of users in an ongoing fashion, hardware troubleshooting, etc.	This is an unknown but could potentially be inclusive of all types of support. Offerors should rely on their interpretation of the SOW based on their knowledge and experience in performing similar types of work.
45.	SOW, Section Two, B.1.f.: In the requirement to "Provide comprehensive data management services to support licensure..." please clarify what is expected of the contractor, especially regarding "… to support licensure ..." e.g., is this referring to providing software licenses?	The reference here is to provide data management services that support licensure of a pharmaceutical product, i.e. validated software, processes and procedures, techniques and analyses accepted by the FDA for consideration of licensure/approval of product.

STATEMENT OF WORK: SECTION TWO – NON-CORE FUNCTIONS		
No.	**Question**	**Answer**
46.	Section Two, B.3.: Will DAIDS further define the workscope for statistical analysis such as numbers of datasets, tables, listings, and figures, or should contractor assume this?	The scope for statistical analysis is not known at this time; therefore, we cannot provide this information.
47.	SOW Section Two, B.4.: How does SOW Section Two, B.4. relate to the DAIDS RFP-NIH-NIAID-DAIDS-04-30, Patient Safety Monitoring in International Laboratories?	This acquisition relates to RFP for Patient Safety Monitoring in that it could supply an additional resource for these services.
48.	SOW Section Two, B.6.i.: Product accountability is generally conducted as part of routine site monitoring visits. Monitoring is generally conducted at intervals >1 month while the requirement is for monthly product accountability reports. Please explain.	The contractor will be directed as to frequency for product accountability reports if the contractor assumes such work.
49.	Section Two, B.7.: For the non-core function of specialized domestic and international clinical trial material shipping section; does this only relate to laboratory specimen shipping and supplies?	This relates to any clinical trial material.
50.	SOW Section Two, B.8.a.: Are protocols expected to be included in translation requirements? (I ask this because this will impact the skill requirement for translators)	There is a potential that it may be necessary to have protocols translated.
51.	The Communications Services tasks (page 19 paragraph B.8.g.) refer to providing web sites as required, while interfacing and linking with relevant entities and sites. Is it assumed that the Contractor will provide web-based communications to international sites? If so, is it assumed that such web-based communication will support multiple languages? Are there any design, security or technical considerations (including bandwidth considerations) associated with web-based communications to the sites?	It is assumed that the contractor will provide web-based communications to international sites, and support multiple languages. We would anticipate the offeror give advice as to any considerations associated with web-based communications.
52.	SOW Section Two, C.1.a.8): What type of "specific topics" is projected for scientific training?	It is anticipated that the contractor will recommend and advise the DAIDS on training topics as training needs emerge.
53.	SOW Section Two, C.1.b.: Does this mean that if we conduct a GCP training session for site personnel in Malawi for instance that it will be our planners who will make all arrangements in Malawi (i.e. finding the venue, coordinating food and transportation) for site personnel and paying for all of the above? Or is this just pertaining to meeting planning for group meetings where site personnel will be flown in?	Yes, it is expected that all meeting, transportation, and lodging costs for training of site personnel will be reimbursed under the contract. Meals are included with the traveler's per diem.

STATEMENT OF WORK: SECTION TWO – NON-CORE FUNCTIONS		
No.	**Question**	**Answer**
54.	The RFP refers to web-based training materials (page 21, C.1.f.). Is it assumed that the web-based training materials are delivered in multiple languages? Is there any requirement for audio or video-based materials, or they assumed to be only text and graphics-based? Are there bandwidth considerations with respect to delivering web-based training to the sites?	It is assumed that web based training materials will be delivered in multiple languages. The formats for training material are unknown at this time but will be determined on a case-by-case basis. We anticipate that there will be bandwidth considerations with respect to web-based training at the sites, and expect the subcontractor will be advising us of these considerations.
55.	SOW Section Two, C.1.g.: Does this mean that we are to maintain training records for all site personnel training for any and all training? In other words, if a nurse in Durban, South Africa goes to an HIV update course at the University in Durban, will she send training materials (certificate, course agenda etc.) to us via our training web site and we will keep track of all professional training for any and all site personnel ("each individual within each Network")? Yes Or is this "central training documentation mechanism" just for us and Network specific training completed by site personnel?	Yes, this means the contractor is to maintain training records for all site personnel for clinical training. The task is set forth in Section 2, C1 and relates to training related to clinical trials compliance.
56.	Section Two, C.2.h.: For the non-core function of specialized regulatory support and activities, item h.; what is meant by facilitate submission of site documents?	Facilitate submission of "site" documents to communicate site readiness to execute a clinical trial.
57.	Section Two, C.2.l.: For the non-core function of specialized regulatory support and activities, item l.; which documents would need to be stored and where would you envision that this happen?	Regulatory files are examples of documents. Documents would be stored either at DAIDS or the contractor's site.
58.	SOW Section Two, C3c: Should it be assumed all monitoring reports from multiple sources for all DAIDS network and non-network clinical sites will be tracked through the web-based database?	No, although that is a desired outcome.
59.	Section Two, C.3.: For the non-core function of Monitoring/Auditing/Quality Assurance Support; there is a statement regarding the staff utilized for monitoring must be independent of site management staff and must have separate reporting lines of authority. Do you expect that this group would not report in to anyone on the project or could they report into one of the core management staff?	It is expected that those involved in monitoring/ auditing/quality assurance functions will report in a way that complies with organizational conflict of interest regulations.
60.	Section Two, C.3.: For the non-core function of Monitoring/Auditing/Quality Assurance Support, item e.; is this function intended to audit other monitoring contracts for the DAIDS?	Yes, there is a potential that audits of other monitoring contractor's work may occur under this contract.

STATEMENT OF WORK: SECTION TWO – NON-CORE FUNCTIONS		
No.	**Question**	**Answer**
61.	SOW Section Two, C.3.: Monitoring staff must be independent of site management staff; can monitoring staff under another contract be detailed to this contract (on an as needed or special assignment basis) for monitoring if awarded?	Offerors are expected to use their own judgment in determining how to best utilize their existing resources to fulfill the requirements of this contract, while at the same time assuring that detailing of staff from their other contracts will not affect their ability to perform under those contracts.
62.	SOW Section Two, C4e: Is it expected that the "other entities to be determined" for SAE reporting will include regulatory authorities (either FDA or its equivalent in the country where the event occurred)?	Yes.
63.	Section Two, C.4.e.: For SAE processing, should we include a safety database and narratives?	No.
64.	Section Two, C.4.: Will the CRO be responsible for regulatory reporting (SAEs) in and outside of the U.S.?	That is not known at this time. Currently the DAIDS utilizes a regulatory compliance contractor; this contractor would be utilized on a case-by-case basis.

SECTION L – INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

No.	Question	Answer
65.	Page 41, Table below "Number of Copies:"-Technical Proposal Appendices: This requires SOPs, Pertinent Manuals, etc. to be provided with the Technical Proposal. We have hundreds of pages of SOPs and manuals that are relevant to the requirements of this RFP. Please clarify what SOPs or manuals the Government desires to be included in the proposal. Also, will the Government remove the requirement to include this material in the page limitation of 150 pages?	Please identify your organizations SOPs and Manuals by topic or title. In addition, please state if the SOPs are currently in use in a particular study and identify the study. It is up to each offeror to determine the importance of the materials to provide with their proposal. We will not be increasing the page limitations.
66.	Page 41, Table below "Number of Copies:"-Is it acceptable to provide all unbound originals, unbound copies, and bound copies in 3-ring binders?	Do not provide the unbound original or the unbound copy in a binder. The remaining 20 bound copies may be provided in the manner your organization chooses.
67.	Section L.1.e, page 48-This section requires questions for the Pre-Proposal Conference to be received on or before July 6, 2004. As proposals are not due until Sept. 17, 2004, will the Government allow additional questions to be submitted after July 6? If yes, can the Government provide an e-mail address for submittal of questions?	There will be additional opportunities to submit questions prior to the established proposal due date. All additional questions must be submitted via e-mail to the Contracting Officer. The CO ad PO will prepare the answers and an updated Q&A Amendment will be posted in the FedBizOpps and on the NIAID CMP Home Page every Friday afternoon between July 30 and September 10.
68.	Page 54, Item 14, please clarify if a small business organization is required to submit a Small Business Subcontracting Plan.	Refer to Page 54, Item 14, subparagraph a), which states" THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS OR NON-U.S. CONCERNS.
69.	7-Page 56, Item L.2.a.14.d)(11): The SB subcontracting goal is 23%. Is this requirement based on a percentage of the overall contract dollar value?	Yes. It is also representative of the sum of the other small business categories. Refer to the guidance provided in the Small Business Subcontracting Plan format.
70.	The subcontracting goals for other categories of SB, such as 5% for SDB and 3% for Service-Disabled Veteran-Owned SB, add up to 19%. Are these goals to be interpreted as being percentages of the 23% SB subcontracting goal or are they percentages of the overall contract dollar value as well? If the latter, then this implies that the overall SB/SDB subcontracting goal is 42%. Is this correct?	The goals established for SDB, and Service Disabled Veteran Owned SB are to be interpreted as percentages of the total 23 percent Small Business Subcontracting Goal.
71.	Technical Proposal Instructions, page 62, (3), Additional Personnel, states. "List names, titles, and proposed duties of additional personnel, if any who will be required for full-time employment, or on a subcontract or consultant basis. This appears to be in conflict with page 84 which states, "You are also directed NOT to propose any specific organizations with which you may plan to subcontract." Does this mean we are not to name specific organizations with whom we might subcontract, but we can name individual subcontractors or consultants. Please advise.	We apologize for providing conflicting information. Please DO NOT identify any subcontractors or consultants. This paragraph will be removed from the RFP in the Amendment.

SECTION L – INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS		
No.	**Question**	**Answer**
72.	Technical Proposal Instructions, page 63 (4) Other Considerations, states "Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include a). Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship." This appears to be in conflict with page 84 "You are also directed NOT to propose any specific organizations with which you may plan to subcontract.." Please advise.	We apologize for providing conflicting information. Please DO NOT identify subcontractors or consultants. We will remove paragraph (4)a) from the RFP in the Amendment.

SECTION M – EVALUATION FACTORS FOR AWARD		
No.	**Question**	**Answer**
73.	With respect to page 84 and the restriction on identifying proposed subcontractors, are offerors allowed to propose identified consultants for performing core and/or non-core functions?	No, you many not identify subcontractors or consultants by name. In the case of consultants you may discuss the types of services you may acquire from a consultant in order to fulfill the requirements of the SOW.

APPENDIX A – TECHNICAL PROPOSAL TABLE OF CONTENTS		
No.	**Question**	**Answer**
74.	Section L.2.a.4, page 51-This paragraph requires that "The technical proposal must include direct cost and resources information …" Where in the Table of Contents specified in Appendix A should we present the direct cost and resources information required by this section of the RFP?	Appendix A, Table of Contents, is being revised to more clearly state how the Technical Proposal should be organized.
75.	Section M.4.C, page 89 and 90-This RFP section provides evaluation criteria for Organizational Experience, Resources and Facilities, however some of the bulleted items to be evaluated (on pages 89 and 90) are not explicitly identified in the Technical Proposal Table of Contents provided in Appendix A. Where in the Table of Contents of App. A should we present the information required for the Government to conduct their evaluation of the items specified in Section M.4.C? Also, Section M.4.C includes evaluation of "facilities." Where in the Table of Contents of App. A should we present facilities?	The Table of Contents will be revised to more clearly state how the Technical Proposal should be organized.
76.	Appendix A, page 3 and Appendix B, page 2-Several of the key and non-key personnel listed in App. A are not included in the labor categories listed in App. B, e.g., Administrative Leader and Senior Physician are not in App. B. Also, some titles are inconsistent between these two appendices, e.g., Senior Project Manager is in App. A while Senior Project Director is in App. B. Please clarify the key/non-key personnel requirements in App. A relative to the labor categories in App. B.	Appendix A and B will be revised to provide clarification.
77.	Appendix A, page 4, Section 5-To avoid duplication of material in this page-limited proposal, please clarify which items/paragraphs in RFP Section L.2.b must be addressed in Section 5 of the proposal. For example, L.2.b requires a "detailed work plan … indicating how each aspect of the statement of work is to be accomplished." Is this expected to be presented in Section 5? Similarly, which subsections of Item 1, Technical Discussions, on page 61 must be addressed?	Section L.2.b. is boilerplate language that is required in all RFPs to provide guidance in preparing proposals. The Appendix A, Table of Contents, has been provided to assure all offerors follow a similar format to allow for easier and consistent review of all proposals. Offerors must use their own discretion in determining the most appropriate place to address these issues within the format provided.
78.	Are offerors requested to submit a cost estimate of the case study in Appendix A? If yes, please specify which proposal (technical or business) should include the estimate, and whether the estimate should be considered part of our total cost in the business proposal.	Offerors are not required to submit a cost estimate for the case study.

APPENDIX B – BUSINESS PROPOSAL (UNIFORM ASSUMPTIONS)		
No.	**Question**	**Answer**
79.	Appendix B, page 1-In Items 2 and 3, the uniform assumptions for Non-Core Functions and Travel for Year 1 sum to $4,630,000 (= 3,230,000 + 1,400,000). Then regarding Item 1, Estimated Total Direct Cost, is our interpretation correct that $8,154,000 (= 12,784,000 – 4,630,000) is the estimated direct cost for core functions in Year 1?	Yes
80.	In Appendix B Page 2, a number of support staff positions and LOE estimates are listed which do not appear necessary to carry out the core functions of the contract specified in the Statement Of Work: Section One: Core Functions. If we are misinterpreting this, could the government specify where in Section One of the SOW the services would apply of the following staff: a. Those listed in the support category, and; (for general research program management support of all tasks conducted within the auspices of this contract) b. GMP expert. 2B4	a. Those listed in the support category, should be titled "Non-Core functions" and; b. The GMP expert is required (as are many other positions) to oversee the specialized work required to be accomplished in the non-core functions.
81.	Appendix B.3.: Are travel expenses for Technical Evaluation Panel Members included in the Uniform Assumptions for Travel, if reimbursable?	Yes.
82.	Appendix B: Estimated Total Direct Cost, The description says that cost will increase by as much as 50% in Years 2 through 5. Does this mean per annum?	Yes.
83.	Appendix B: Should the monies listed in the RFP for the non-core functions be listed separately in the budget template and should they be absent of any additional fees?	Non-Core costs should be listed separately. Fees and indirect costs associated with non-core costs should be applied based on the organization normal business practices.
84.	Is the offeror expected to provide names for all the positions listed on the table noted in appendix B in our proposal?	Yes.

APPENDIX E		
No.	**Question**	**Answer**
85.	Appendix E: Are the trials listed on the chart entitled "Investigator-Initiated Trials (Non-Network)" to be included in the management of this proposal?	Yes.
86.	12-Appendix E-Re: the second table in App. E titled Potential HIV Vaccine Efficacy Trial: (a) Please identify the heading for the 7th column. (b) Are columns 6 and 7 parts of pII? (c) In column 11, what does "vol" mean? (d) In column 12, please identify HS and MSM	(a) The heading for the 7th column. = N (b) Are columns 6 and 7 parts of pII? Yes 3 yr duration, and N (c) In column 11, "vol" = volunteers (d) In column 12, HS = Heterosexual, MSM = Men having sex with men.

DAIDS ENTERPRISE SYSTEM / INFORMATION TECHNOLOGY		
No.	**Question**	**Answer**
87.	The RFP refers to "data exchange guidelines and a set of platform technology standards." (p. 6). Are these guidelines and standards already defined, and if so, may we receive a copy? We would need to know the technology platform standards in order to cost any task or function related to data exchange.	Please see Appendix D and Appendix F for additional information. [Note: Appendix F will be made available with Amendment 2]
88.	With respect to data exchange guidelines and standards, are there any already-defined programming or security standards (other than the use of XML)? May we receive them?	Please see Appendix F and DAIDS-ES Standards: [Note: Appendix F will be made available with Amendment 2] With regards to security standards please refer to the Computer Security Act and OMB Circular A-130 at http://www.whitehouse.gov/omb/circulars/a130/a130appendix_iii.html [Note: Appendix G will include DAIDS-ES Standards and will be made available with Amendment 2]
89.	Is it assumed that the Contractor will maintain a separate technology infrastructure for this project, i.e. separate servers, software licenses etc.? Or, alternatively, may the infrastructure be shared with other projects the Contractor may be performing?	Please see Appendix F and Appendix G. [Note: Appendices F and G will include DAIDS-ES Standards and will be made available with Amendment 2]
90.	Appendix D refers to a Memorandum of Understanding that will detail such issues as security concerns, rules for interconnecting applications and systems, data sharing etc. Are the rules or standards already defined? May we see a sample or representative MOA that addresses these items?	Appendix D gives the most current information on the MOU/MOA process. No sample is available at this time.
91.	With respect to data exchange (Appendix D page 2); are there data encryption standards or other data transmission/security requirements? What are they?	The DAIDS-ES is following HHS defined "Consolidated Health Informatics Standards". See attached. For encryption standards, please refer to FIPS 186, Digital Signature Standard and FIPS 180-1, Secure Hash Standard issued by NIST and NIH Certificate for SSL V3.1. - RSA 1024 bits, SHA. [Note: Appendix H, CHI Standards, will be made available with Amendment #2]

DAIDS ENTERPRISE SYSTEM / INFORMATION TECHNOLOGY		
No.	**Question**	**Answer**
92.	The RFP lists comprehensive data management capabilities that the contractor must provide, and which shall interface with DAIDS-ES and other network and non-network data management centers (p. 16 section B.1.f.) Are the data interface standards for each function defined? May we receive copies?	The attached spreadsheet provided you with an explanation as to the data interface standards. CHI standards are being applied within the DAIDS-ES system for various clinical data management functions. [Note: Appendix G will include DAIDS-ES Standards and will be made available with Amendment 2]
93.	In reference to Section One, Core Functions, please provide the data exchange guidelines and a set of platform technology standards.	Please see Appendix F and Appendix G.. [Note: Appendix G will include DAIDS-ES Standards and will be made available with Amendment 2]
94.	Please provide detailed technical information about the DAIDS Enterprise System.	Please see Appendix D and Appendix F for additional information. [Note: Appendix F will be made available with Amendment 2]
95.	SOW Section Two C, 3: Section 3c in Statement of Work states: "Design, implement and manage a web-based database to track monitoring visits and action items, deficiencies, and resolution(s). This shall be performed in cooperation with DAIDS-Enterprise System...." Can you define the term 'cooperation' further? Would this mean providing interfaces of data from our systems to the DAIDS-ES and working with them to achieve this?	Cooperation can be defined as collaboration. Please see Appendix F for information on interface. [Note: Appendix F will be made available with Amendment 2]
96.	SOW Section A, 3c: Will this initial listing be inclusive of legacy data or current status only? If legacy data is to be included, how far back will it be expected that the contractor will go to collect this data? And finally, how will this task be shared with the DAIDS-ES, as it appears there is some overlap between this task for the contractor and the expectation for the DAIDS-ES, to house this type of data.	Initial listings may be inclusive of legacy data although the date of such data is not known at this time. The DAIDS-ES will function as described in Appendix D and Appendix F. It is anticipated that this contractor will have intense overlap in many tasks. [Note: Appendix F will be made available with Amendment 2]
97.	SOW Section Two, C3b: This section addresses reviewing the work output of other contractors and linking it with the DAIDS ES. Can you please identify the scope (approximate numbers of reports and approximate numbers of other contractors) of the expected review of the monitoring reports of other contractors?	It is anticipated that there will be at least one monitoring contract and potentially two. During the last 12 months there were approximately 1250 monitoring reports. The DAIDS-ES is currently working with monitoring contractors and the linkage of the DAIDS-ES to monitoring contractors.

DAIDS ENTERPRISE SYSTEM / INFORMATION TECHNOLOGY		
No.	**Question**	**Answer**
98.	We wish to use an information management system to support our performance of the core clinical program management tasks. Is it acceptable to contract with a software vendor to use their information management system, and to have the vendor provide hosting services for the application? May we also name that system and software vendor in our proposal?	The successful offeror must be in full control of the information systems utilized to perform the core functions. Offerors must use their own judgment in determining if their technical approach will fulfill the requirements of the Mandatory Criteria.

ADDITIONAL QUESTIONS – 2nd Posting (09/08/2004)		
No.	**Question**	**Answer**
99.	Re: p. 59 (19) a p. 90-91, item 5 Appendix A, page 6, Section 7 The sections referenced provide conflicting direction regarding the location of the past performance response. Page 59, item (19) a, indicates that past performance information is to be submitted as part of the business proposal. Consistent with that, pages 90-91 (Section M) list the Past Performance Factor for evaluation outside of the Technical Evaluation Criteria. Appendix A, page 6, however, defines Section 7 of the Technical Proposal to be the past performance response. This Offeror assumes that Appendix A, page 6, is in error, and that the past performance response should be included as part of the business proposal. Please confirm.	Offerors are required to submit their past performance information in their Business Proposals.
100.	Please confirm that the following standard forms (required by the government) are excluded from the Technical Proposal page count: Technical Proposal Cover Sheet NIH-1688-1, Project Objectives Technical Proposal Cost Information Summary of Related Activities Optional Form 310, Protection of Human Subjects Government Notice of Handling Proposals Targeted/Planned Enrollment Table	The referenced standard forms are included in the 150 page limitation for the Technical Proposal. Please refer to Page 41 of the RFP, entitled PROPOSAL SUBMISSION: NUMBER OF COPIES, PAGE LIMITATIONS AND ELECTRONIC FILE SIZE, last paragraph which states: "Total page count does **not** include: 1 Cover and Back Page; 1 Table of Contents; Section Dividers that do not contain information other than title of Section.
101.	Please confirm that transmittal letter is excluded from the page count of the Technical and Business proposals.	A transmittal letter will be included in the 150 page limitation of both the Technical and Business proposals. Please refer to Page 41 of the RFP, entitled PROPOSAL SUBMISSION: NUMBER OF COPIES, PAGE LIMITATIONS AND ELECTRONIC FILE SIZE, last paragraph which states: "Total page count does **not** include: 1 Cover and Back Page; 1 Table of Contents; Section Dividers that do not contain information other than title of Section.
102.	Please confirm that the cover page of the Technical and Business Proposals is excluded from page count.	Please refer to Page 41 of the RFP, entitled PROPOSAL SUBMISSION: NUMBER OF COPIES, PAGE LIMITATIONS AND ELECTRONIC FILE SIZE, last paragraph which states: "Total page count does **not** include: 1 Cover and Back Page; 1 Table of Contents; Section Dividers that do not contain information other than title of Section.

ADDITIONAL QUESTIONS – 2nd Posting (09/08/2004)		
No.	**Question**	**Answer**
103.	Please confirm that the following standard form (required by the government) is excluded from the Business Proposal page count: NIH-2043, Proposal Summary and Data Record (Business Proposal Cover Sheet)	The referenced standard form is included in the 150 page limitation for the Business Proposal. Please refer to Page 41 of the RFP, entitled PROPOSAL SUBMISSION: NUMBER OF COPIES, PAGE LIMITATIONS AND ELECTRONIC FILE SIZE, last parargrpaph which states: "Total page count does **not** include: 1 Cover and Back Page; 1 Table of Contents; Section Dividers that do not contain information other than title of Section.
104.	Please confirm that RFP compliance matrices and acronym lists, if provided to assist evaluators in reviewing the proposals, are excluded from the page count for the Technical and Business Proposals.	The items addressed in this question (RFP matrices and acronym lists) are included in the 150 page limitation.
105.	Re: Appendix A, page 6, item 4 Page 89, item C Page 80, item (3) b The sections referenced above provide conflicting direction regarding the location and scope of the required "Organization Experience, Resources, and Facilities" response. Appendix A, page 6, item 4 indicates that an "Organizational Experience, Resources and Facilities" response is required within the Technical Proposal. Page 89, item C, identifies the Section M evaluation criteria related to "Organizational Experience, Resources and Facilities", however, Section L provides no corresponding instructions regarding what is to be addressed within such an "Organizational Experience, Resources and Facilities" response. Furthermore, it appears that the government is requesting organizational experience responses in both the Technical and Business proposals. "Organizational Experience Related to the RFP" is required as part of the "Qualifications of the Offeror" response in the Business Proposal (please see page 80, item (3) b). This requirement does not include the topics of resources and facilities. This Offeror requests that the government: (1) Provide the Section L requirements for the "Organizational Experience, Resources and Facilities" Technical Proposal response Clarify whether Organizational Experience responses are required in both the Technical and Business proposals.	The referenced items address distinctly different aspects of the offerors ability to accomplish the work required from business and technical standpoints. Page 89, item C (SECTION M – EVALUATION CRITERIA, SECTION 4 TECHNICAL EVALUATION CRITERIA) (ORGANIZATIONAL RESOURCES AND FACILITIES) outlines how the NIAID will evaluate the offerors **technical experience and abilities** in accomplishing efforts of similar size and scope to this acquisition. Offerors should provide their response in the TECHNICAL PROPOSAL. Page 80, item (3)(b) (SECTION L – INSTRUCTIONS, CONDITIONS AND NOTICIES TO OFFERORS, C. BUSINESS PROPOSAL INSTRUCTIONS, (3) QUALIFICATION OF THE OFFEROR) relates to the offerors **business experience and abilities** to perform relative to cost and delivery schedules on efforts of similar size and scope to this acquisition. Offerors should provide their response in the BUSINESS PROPOSAL. Appendix A, was provided as a template to assist offerors in preparing their Technical Proposals. In cases where further clarification of the information that would be required by the offerors was necessary, greater detail was provided. In the case of the evaluation criteria entitled "ORGANIZATIONAL RESOURCES AND FACILITIES" no clarification was deemed necessary. It is expected that all offerors will address all aspects of the requirements identified in SECTION L and provide the necessary evidence so that their technical experience and capabilities can be evaluated as outlined in the Technical Evaluation Criteria.

ADDITIONAL QUESTIONS – 2nd Posting (09/08/2004)		
No.	**Question**	**Answer**
106.	Please confirm that with the changes listed in Appendix B of Amendment #2 concerning the estimated projected staffing, we are still to use a year one estimate of total costs at $12.784M (including non-core functions and travel) and are to use an annual growth rate projection of 50% for the years 2 through 5.	Yes, you are to use the same assumptions provided in Appendix B.
107.	Amendment No. 2, Section 3 - PERSONNEL/STAFFING, Subparagraph b and c - Other Personnel (Non-key). & Technical and Administrative Staff Should the Offerors identification of any project personnel and discussion of their related experience include labor categories in the first year only? While the offeror has capacity to provide additional resources as demands for the project increase in years 2 through 5, providing specific individuals that will be available for work commencing in June 2006 is difficult to do in good faith.	Offerors responses should address all labor categories identified for years 1-5. The categories and number of hours anticipated are provided as estimates. There is a potential that the government may require some of the labor categories identified prior to years 2-5. We appreciate the difficulty in identifying individuals for future requirements, and understand that they may, or may not be available in the distant future.
108.	Re: Page 52, item 11 Appendix A Appendix A does not list a data sharing plan within the Table of Contents for the Technical Proposal, however, page 52, item 11 (within Section L.2.a), indicates that the "offeror must submit a plan for data sharing or state why data sharing is not possible". Please clarify whether this data sharing response is required and, if so, please confirm that it should be included as part of the Technical Proposal.	A data sharing plan is not required at this time. In the event the work under the contract does generate the types of data that will make require a data sharing plan, the contract will be modified as necessary.
109.	Additional Business Instructions (Appendix B), Item 4. Estimate of effort, as revised by Amendment 2 incorrectly shows a total of 18 Full Time Employees (FTEs). The total is actually 19 FTEs. Please advise.	Please see the attached and corrected excerpt from Appendix B. The attached replaces the Table under paragraph 4., "Estimate of Effort (Core Functions ONLY)."

Replaces Table in paragraph 4., of Appendix B:

CORE FUNCTIONS ONLY					
	YEAR 1			YEARS 2-5 (Avg.)	
Labor Category	**Estimated Hours**	**Estimated FTEs**		**Estimated Hours**	**Estimated FTEs**
Professional and Technical Staff					
Program Director	1880	1		1880	1
Deputy Program Director	1880	1		1880	1
Senior Regulatory Director	1880	1		1880	1
Clinical Trial Specialist/Operations	0	0		9400	5
Floating Project/Site Manager	0	0		9400	5
Financial Managers	0	0		5640	3
Lead Monitor	1880	1		1880	1
Regulatory Affairs Specialist	1880	1		18800	1
Contracts Specialist	1880	1		5640	3
Recruitment Specialist	0	0		3760	2
Purchasing and Logistics	1880	1		5640	3
Travel Specialist	1880	1		3760	2
Senior Physician	1880	1		1880	1
Lead Trainer	1880	1		1880	1
Legal Specialist	1880	1		1880	1
Senior IT Specialist	1880	1		1880	1
IT Support	3760	2		3760	2
HR Specialist	1880	1		1880	1
Project Assistants	1880	1		9400	5
Central File Clerks	1880	1		7520	4
Facility (Lab)/GMP expert	1880	1		1880	1
TOTAL Professional/Technical Staff:	**33840**	**18**		**84600**	**45**